Department of Defense Healthcare Provider's Brief

ANTHRAX VACCINE

18 Aug 09

Briefing Outline

- Key Messages
- Policy
- Threat
- Disease
- Vaccine
- Dosage Schedule and Route of Administration
- Exemptions
- Expected Local Adverse Reactions
- Storage and Handling
- Immunization Documentation
- Contacts

Key Messages

- Your health and safety is our top concern
- Receiving the vaccination is the only around-the-clock protection available for service members against this very real threat
- The Food and Drug Administration says the anthrax vaccine protects against all forms of anthrax disease and is safe
- Vaccination protects you, your unit, and your mission

Policy History of the AVIP

- Dec 97: Secretary of Defense ordered the AVIP
- Mar 98: Vaccinations began in Southwest Asia
- Aug 98: Vaccinations began in Korea
- 2000-01: Slowdowns due to shortage. After supply restored, program resumed in 2002
- Oct 04: Injunction issued against DoD
- Jan 05: FDA issues Emergency Use Authorization (EUA)
- Dec 05: FDA formally issues Final Rule/Final Order
- Oct 06: Deputy Secretary of Defense issued AVIP policy to re-establish a mandatory program for those in higher risk areas and with special roles; policy allows voluntary vaccinations for other groups
- Dec 06: Under Secretary of Defense for Personnel and Readiness released DoD implementation guidance for the AVIP policy
- Dec 08: Vaccine route and dosing schedule change

Current Policy Implementation

Mandatory and Voluntary Vaccinations

- Vaccinations are mandatory for DoD service members, emergency essential designated civilians, and contractor personnel performing mission-essential services assigned to:
  - Central Command area of responsibility, the Korean Peninsula, and the Horn of Africa for 15 or more consecutive days
  - Special units with biowarfare or bioterrorism related missions
  - Specialty units with approved exception to policy
- Vaccinations shall begin, to the extent feasible, up to 120 days prior to deployment or arrival in higher threat areas

Current Policy Implementation

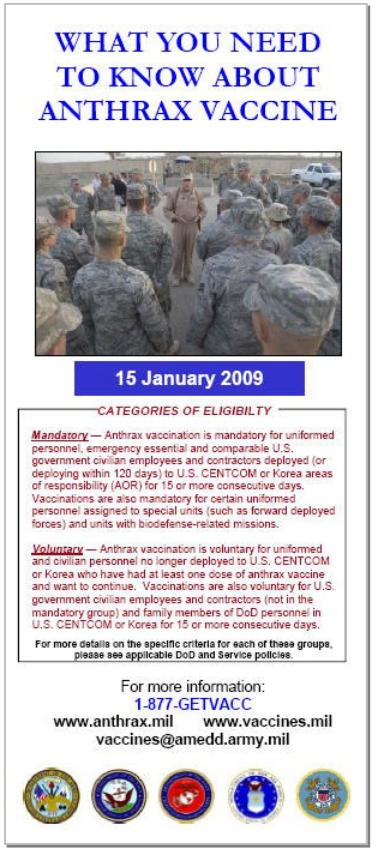
- Vaccinations are voluntary for DoD service members who are not in the mandatory groups and have received at least one dose of Anthrax Vaccine Adsorbed during or after 1998

- Vaccinations are voluntary for DoD civilians and adult family members; contractors and their accompanying US citizen family members:
  - Residing in Central Command area of responsibility, the Korean Peninsula, and the Horn of Africa for 15 or more consecutive days

- DoD Civilian Personnel Management Service concluded notification to national unions on 12 Jan 07

Current Policy Implementation

- Ensure ALL potential vaccine recipients receive the most current educational trifold brochure available, dated 15 Jan 2009 or later
- Ensure an Individual's Briefing is available at all immunization sites
- Educate potential vaccine recipients about anthrax threat and benefits, plus risks of vaccination
- Screen potential vaccine recipients to confirm eligibility and potential medically exempt personnel



WHAT YOU NEED TO KNOW ABOUT ANTHRAX VACCINE

15 January 2009

CATEGORIES OF ELIGIBILTY

Mandatory — Anthrax vaccination is mandatory for uniformed personnel, emergency essential and comparable U.S. government civilian employees and contractors deployed (or deploying within 120 days) to U.S. CENTCOM or Korea areas of responsibility (AOR) for 15 or more consecutive days. Vaccinations are also mandatory for certain uniformed personnel assigned to special units (such as forward deployed forces) and units with biodefense-related missions.

Voluntary — Anthrax vaccination is voluntary for uniformed and civilian personnel no longer deployed to U.S. CENTCOM or Korea who have had at least one dose of anthrax vaccine and want to continue. Vaccinations are also voluntary for U.S. government civilian employees and contractors (not in the mandatory group) and family members of DoD personnel in U.S. CENTCOM or Korea for 15 or more consecutive days.

For more details on the specific criteria for each of these groups, please see applicable DoD and Service policies.

For more information:
1-877-GETVACC
www.anthrax.mil www.vaccines.mil
vaccines@amedd.army.mil

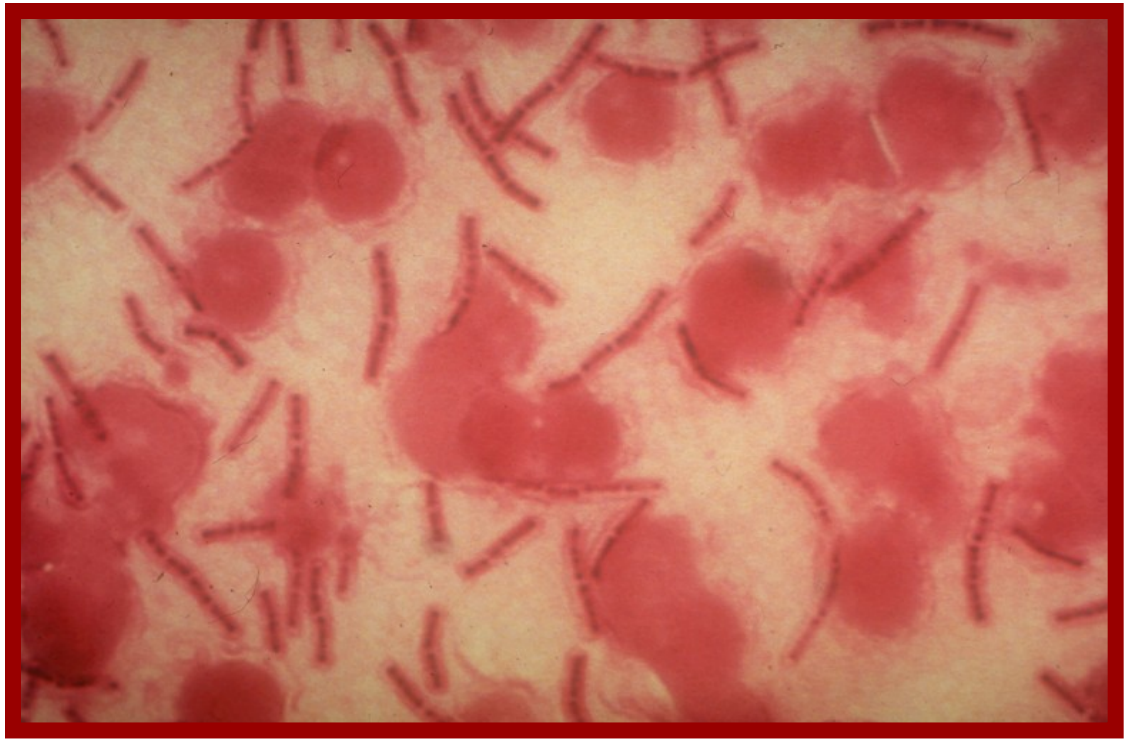
Threat

- Inhalation anthrax is 99% lethal if unprotected, unvaccinated, or untreated
- Anthrax spores are the most likely bioweapon
  - Relatively easy and cheap to produce
  - Extremely stable – can withstand harsh environmental conditions and remain dormant up to 50 years
  - Can be aerosolized and delivered in a variety of methods
  - Odorless, colorless, tasteless, difficult to detect

Anthrax Infections

- Recognized as an illness for centuries
- Once common where livestock were raised, now controlled using vaccine for livestock
- Human infection from direct contact with infected animals, animal products, or anthrax spores
- Still a problem in Asia and Africa
- Terror attacks via US mail in Fall 2001

Microbiology of Anthrax

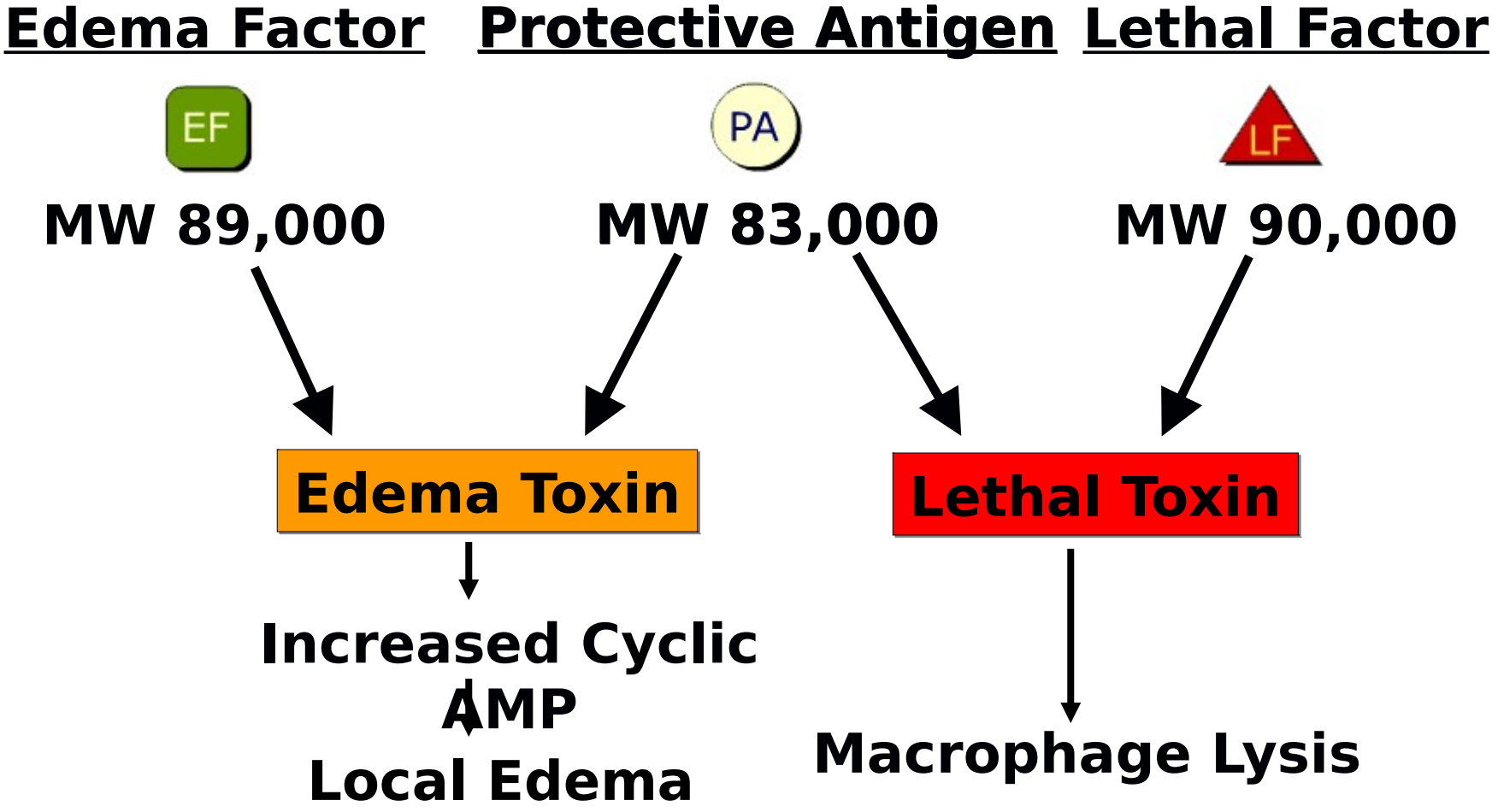


Gram-positive spore-forming rod

Pathogenesis

- Spore enters through broken skin, gastrointestinal tract, or lung
- Ingested by macrophages
- Transported to regional lymph nodes
- Germinates in regional nodes
- Local production of toxins cause edema & necrosis of tissue
- Septicemia & toxemia
- Seeding of other organ systems

Anthrax Toxins: Building Blocks & Effects

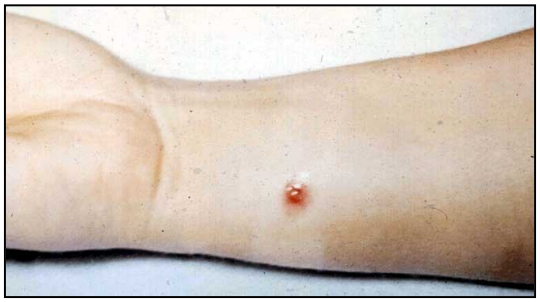


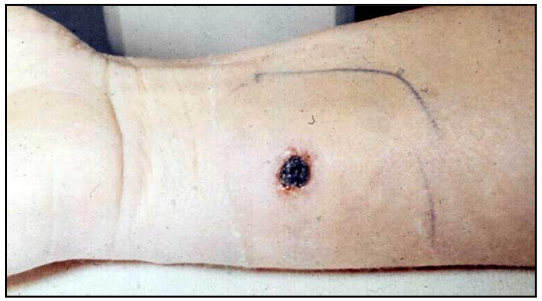
Infections

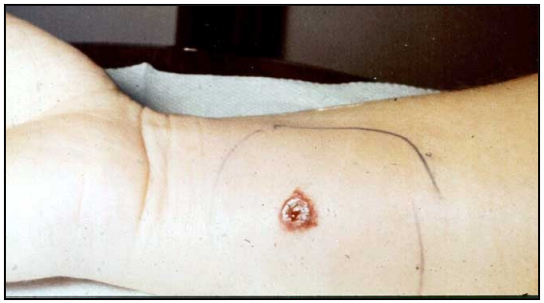
- Three types of anthrax infection
  - Cutaneous anthrax (skin)
  - Gastrointestinal anthrax (GI tract)
  - Inhalational anthrax (lungs)

Cutaneous Anthrax

- Cutaneous: Contact with spore-infected animal hides or products through a break in the skin
- Incubation period: 1-5 days
- Symptoms: Papule forms in 1-2 days; changes to vesicle; ruptures to form ulcer and develops black eschar (scab); lasts 2-3 weeks







Gastrointestinal Anthrax

- Gastrointestinal: Ingesting poorly- or undercooked infected meat
- Incubation period: 2-5 days
- Symptoms: Fever, abdominal pain, nausea, vomiting of blood, and bloody diarrhea
- Oropharyngeal anthrax -> compromised airway
- Mortality up to 25-60%

Inhalation Anthrax

- Inhalation: Spores enter lungs; ingested by macrophages, migrate to lymph nodes. Spores germinate, rapidly multiply and produce toxins
- Incubation period: 1-6 days
- Symptoms:
  - Initially flu-like: Mild fever, myalgias and malaise, cough, chest discomfort, 2-4 days
  - Slight improvement, hours to days
  - Severe respiratory distress quickly progresses to shock and death in hours to days
- Toxins cause destruction of pulmonary and thoracic tissues, result in multiple organ failure

Diagnosis of Inhalation Anthrax

- Initial symptoms nonspecific
- Development of respiratory distress
  - Chest X-ray with widened mediastinum
  - Usually no infiltrates
- Sputum not helpful; spores settle in tissue
- Hemorrhagic pleural effusion or meningitis
- Blood cultures: Positive late in course of illness

Inhalation Anthrax Treatment

- Early IV antibiotics and intensive care required
  - Mortality may still reach 45% to 80%
- Current treatment of choice (2001—multi-antibiotic therapy):
  - Ciprofloxacin 400 mg IV q 8-12 h
  - Doxycycline 200 mg IV x 1, then 100 mg IV q 12 h
- Disease not spread by respiratory secretions
  - Use ‘Standard Precautions’
- Clinical Issues
  - *Emerging Infectious Diseases*, Bioterrorism-Related Anthrax, October 2002 theme issue

Post-Exposure Prophylaxis

- Inhalation or GI anthrax: IV ciprofloxacin or doxycycline and additional 1-2 antibiotics with activity against anthrax (60 days)
- Cutaneous anthrax: Oral ciprofloxacin or doxycycline; oral penicillin used historically (60 days if suspect bioterrorism; 7-10 days natural infection)
- Post-exposure prophylaxis
  - Oral ciprofloxacin or doxycycline (60 days)
  - Studies show antibiotics plus anthrax vaccine most beneficial
- Antibiotics are still indicated even when fully immunized

Treat as early as suspected; intensive supportive care

Anthrax Vaccine Facts

- Licensed by the Federal government since 1970
  - Administered in US to at-risk veterinarians, laboratory workers, and livestock handlers
  - Over 8.9 million doses to more than 2.2 million people since Mar 98
- Vaccine primes immune system to fight anthrax
- Manufactured in US by Emergent BioSolutions
  - "AVA," *BioThrax*™. Package insert with each vial.
  - Official name: Anthrax Vaccine Adsorbed

This vaccine contains no whole or live anthrax bacteria; therefore, it is impossible to contract the disease from it.

Independent Scientific Reviews

- FDA Advisory Panel on Bacterial Vaccines and Toxoids (*Federal Register,* 1985)
- Defense Health Board (DHB), advising DoD, 1994 to present
- Cochrane Collaboration, Oxford (*Vaccine,* 1998; 2004)
- Working Group on Civilian Biodefense (*JAMA,* 1999, 2002)
- CDC's Advisory Committee on Immunization Practices (ACIP) (*MMWR,* 2000)
- Anthrax Vaccine Expert Committee (AVEC) (*Pharmacoepidemiology & Drug Safety* 2002, 2004)
- National Academy of Sciences (IOM), 2002
- FDA Review of VAERS reports supporting FDA's Final Rule and Final Order (2005)
- Adverse events after anthrax vaccination reported to VAERS, 1990-2007, (*Vaccine*, 2009)

Vaccine Efficacy in Humans

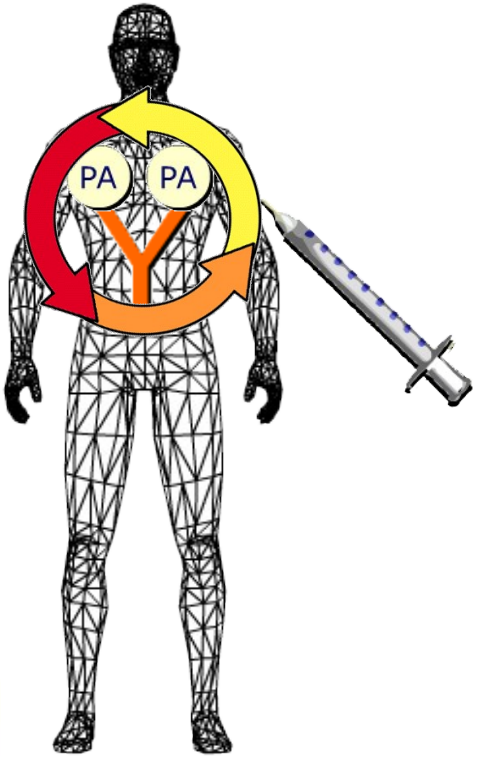
- Brachman et al. *Am J Public Health* 1962;52:432-45
  - Efficacy: 92.5% (95% CI: 65-100%), jointly against cutaneous and inhalation anthrax (table 8)
  - Inhalation anthrax:
    - 5 cases / 448 unvaccinated people
    - 0 cases / 149 vaccinated people
  - Manufacturing improvements, 1960s CDC study
    - Microaerophilic, more PA, less EF and LF
  - Safety and efficacy reaffirmed by FDA advisory panel, *Federal Register* 1985; 50:51002-117
  - Repeated in Final Order issued by FDA, 19 Dec 05

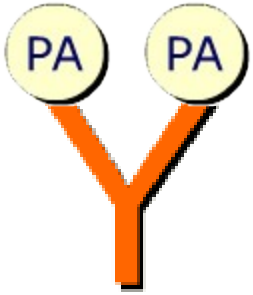
Inhalation Anthrax

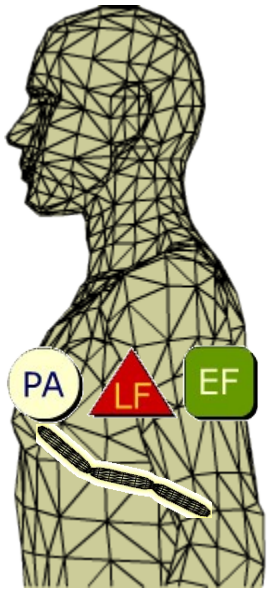
- 55 monkeys vaccinated twice
  - Challenged with spore aerosol, dozens to thousands of times the median lethal dose, 8, 16, 38, or 100 wks later
  - 52 survived. All unvaccinated control monkeys died
- 10 monkeys vaccinated once
  - Challenged with virulent spores 6 weeks later
  - All survived. All unvaccinated control monkeys died
- Overall, 62 of 65 survived, 95% vaccine protective efficacy against inhaled anthrax spore challenge
- Correlates of immunity to infer from animal to humans have not been fully developed

95% survival rate

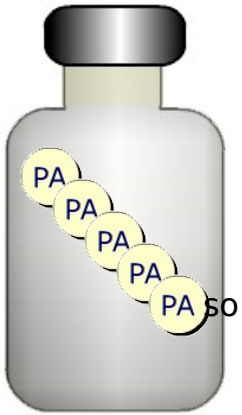
How Anthrax Vaccine Prevents Disease





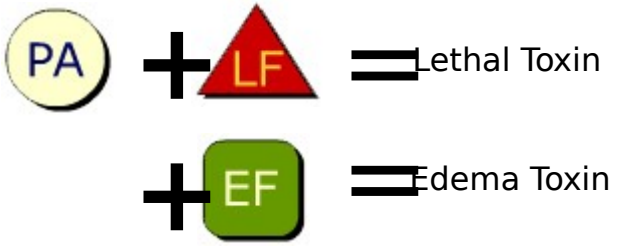


FILTER



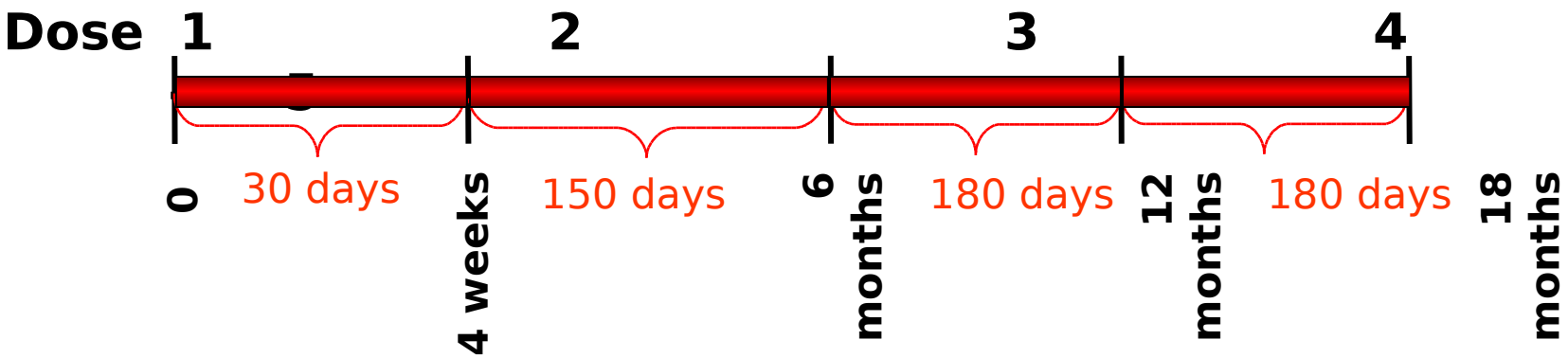
Anthrax vaccine is filtered,
so that it does not contain whole bacteria.

Therefore, anthrax vaccine
Cannot give you the disease.

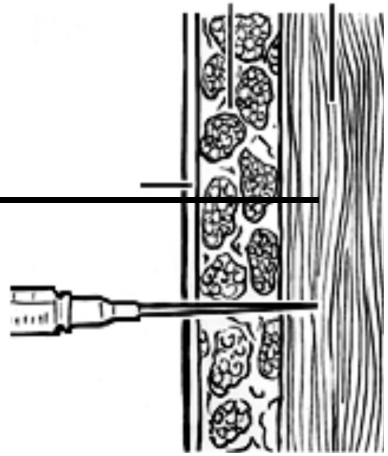


Immunization Schedule

- 5 doses over 18 months, then annual booster
- Do not compress schedule
- Adjust schedule for individual delays
- Do not “restart” series if it has been interrupted

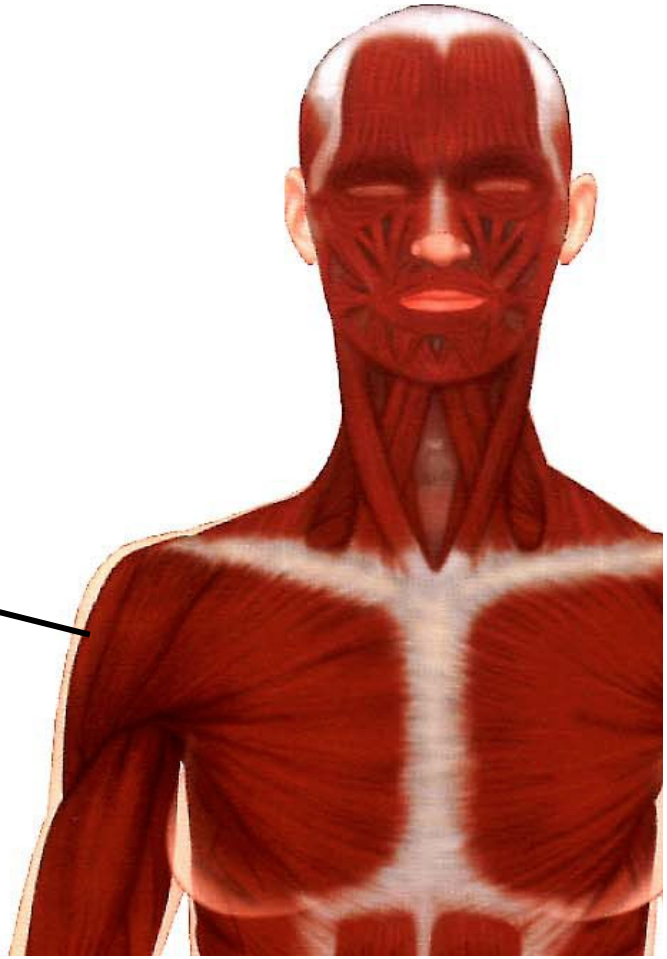


Injection Technique



Intramuscular Tissue

Deltoid Area



Injection over deltoid rather than triceps is preferred, in case of swelling

Exemptions from Vaccination

TEMPORARY PERMANENT

- Some people should not get anthrax vaccine
- Temporary medical exemptions include
  - Women who are pregnant, or uncertain if pregnant
  - Short-term immune suppression
  - Acute diseases, surgery
  - Medical evaluation or condition pending
- Permanent exemptions can include
  - Severe allergic reaction or other serious reaction after a previous dose of anthrax vaccine
  - People with a history of severe latex sensitivity
  - HIV infection or other chronic immune deficiencies
  - People who had Guillain-Barré Syndrome

Anthrax vaccine is licensed for individuals from 18 to 65 years of age

Pregnancy

According to the CDC's Advisory Committee on Immunization Practices (ACIP):

"there is no convincing evidence of risk from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids."

- Vaccinations routinely deferred during pregnancy
- Before vaccination, ask each woman if she is pregnant or if there is the possibility of trying to become pregnant
- No reason to delay conception after vaccination
  - Anthrax-vaccinated & -unvaccinated women at Fort Stewart (*JAMA*, 2002): same rates of conception, delivery
  - Anthrax-vaccinated & -unvaccinated men at fertility clinic: same sperm concentration, rate of pregnancy
- Vaccination during pregnancy
  - Do not vaccinate pregnant women unless potential benefits of vaccination outweigh potential risk to fetus

Injection Site Reactions

Many may experience temporary pain and swelling after the shot

Mild side effects such as redness and tenderness at the site of vaccination are co

- For both genders, IM administration significantly reduces adverse events at injection sites
- Monitoring of all adverse events
  - Burning
  - Soreness
  - Redness
  - Itching
  - Swelling
  - Local pain at the injection site

You can call the DoD Vaccine Clinical Call Center 866.210.6469

Managing Adverse Events After Any Vaccination

Minimizing injection-site reactions and systemic events

- Screen for previous adverse reactions
- Do not give next dose if side effects persist from previous vaccination
- Issue temporary exemption if symptoms persist
- Treat (and pre-treat) adverse events
- Consult healthcare provider skilled in diagnosis and management of vaccine adverse events for permanent exemption

VHC
Vaccine Healthcare Centers Network

www.vhcinfo.org

Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
  - FDA and CDC review 100% of adverse-event reports
  - All VAERS forms reviewed by independent panel of expert civilian physicians for 4 years
- DoD requires healthcare workers submit a VAERS Form for
  - Loss of duty 24 hours or longer (≥ 1 duty day)
  - Hospitalization
  - Suspected vaccine vial contamination
- Other submissions are encouraged
- Anyone can submit a VAERS Form

When in doubt, report it!

1-800-822-7967

www.vaers.hhs.gov

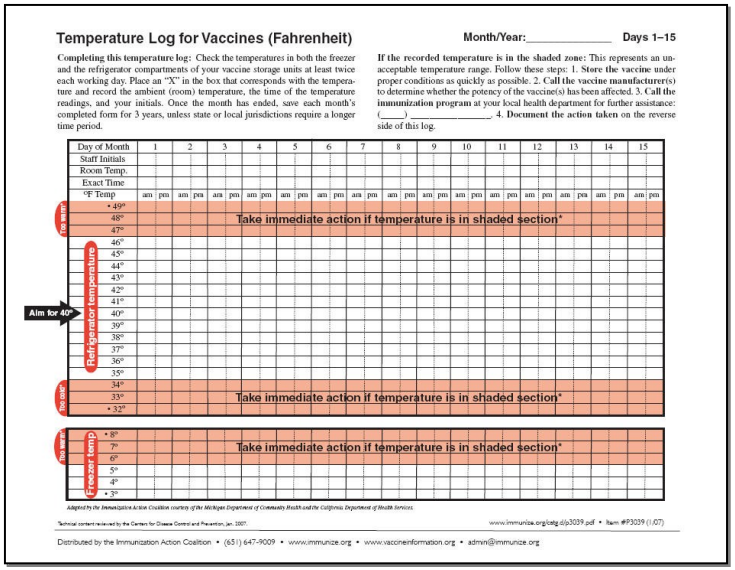
Reserve Component Adverse Event Guidance

- If someone experiences an adverse event in a non-duty status that is possibly associated with a vaccination
  - Should seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
  - Should Report the event to your unit Commander or designated representative as soon as possible
  - Should see local medical department or squadron for guidance
- Commander will determine Line of Duty and/or Notice of Eligibility status, if required
- Submit VAERS for any suspected adverse event

888-647-6676

www.tricare.mil/tma/MMSO

Storage and Handling



Temperature Log for Vaccines (Fahrenheit)

Month/Year:_____ Days 1–15

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month's completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1. **Store the vaccine** under proper conditions as quickly as possible. 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected. 3. **Call the immunization program** at your local health department for further assistance: (____) _____. 4. **Document the action taken** on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Room Temp.															
Exact Time															
°F Temp	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Too Warm	• 49°	Take immediate action if temperature is in shaded section*													
	48°														
	47°														
Refrigerator temperature	46°														
	45°														
	44°														
	43°														
Aim for 40°	42°														
	41°														
	40°														
	39°														
	38°														
	37°														
	36°														
	35°														
Too Cold	34°	Take immediate action if temperature is in shaded section*													
	33°														
	• 32°														
Too Warm	• 8°	Take immediate action if temperature is in shaded section*													
Freezer temp.	7°														
	6°														
	5°														
	4°														
	• 3°														

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Technical content reviewed by the Centers for Disease Control and Prevention, Jan. 2007.

www.immunize.org/catg.d/p3039.pdf • Item #P3039 (1.07)

Distributed by the Immunization Action Coalition • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org • admin@immunize.org

- Keep anthrax vaccine refrigerated
  - Store between 2° to 8° C (36° to 46° F)
  - Temperature check twice a day, even with alarm system
  - Keep logs for up to three years
  - DO NOT FREEZE
- Once vial opened, use until expiration date
  - Do not pre-filling vaccine into syringes
- Storage devices
  - Medical Grade/Household refrigerator
  - VaxiCool or VaxiPac

www.usamma.army.mil/vaccines/anthrax/antxhome.cfm

Record Keeping

- Automated immunization tracking (primary)
  - Service systems and DEERS central repository
  - Do not give any vaccination more than 4 days early
- Written entries
  - Required documentation
  - Deployable Medical Record; Adult Preventive & Chronic Care Flowsheet (DD Form 2766, DD Form 2766C)

Date immunized
Name of vaccine
Manufacturer
Lot number
Series number
Dosage
Vaccinator's name
VIS date

Conclusion

- Anthrax spores are a lethal threat to our forces
- FDA has repeatedly said the anthrax vaccine is safe and effective
- The life-saving benefits of anthrax vaccine make this an essential immunization program
- For service members to understand the value of anthrax vaccination, they need your help
- Make sure service members understand the anthrax vaccine dosing schedule – remind them when their next vaccination in the series is due
- Expeditiously assist anyone experiencing an adverse event in getting proper medical care and advice

Resources

- **MILVAX Agency**
  - www.vaccines.mil
  - www.anthrax.mil
  - www.vaccines.mil/anthrax
  - vaccines@amedd.army.mil
  - 877.GET.VACC
- **DoD Vaccine Clinical Call Center**
  - 866.210.6469
- **Vaccine Healthcare Centers** *for help with adverse event management*
  - www.vhcinfo.org
  - 202.782.0411
- **Information for Civilian Healthcare Providers**

  Call the Military Treatment Facility (MTF) where the member is enrolled OR contact the Military Medical Support Office (MMSO)
  - www.tricare.mil/tma/MMSO
  - 888.647.6676 *if the member is not enrolled to an MTF*
- **USAMMA DOC**
  - www.usamma.army.mil
  - 301.619.4318

Closing

www.vaccines.mil